(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 132 632**
A2

(12) # EUROPEAN PATENT APPLICATION

(21) Application number: 84107687.0

(22) Date of filing: 03.07.84

(51) Int.Cl.⁴: A 61 J 1/00
A 61 M 5/14

(30) Priority: 21.07.83 US 515739

(43) Date of publication of application:
13.02.85 Bulletin 85/7

(84) Designated Contracting States:
DE FR GB IT

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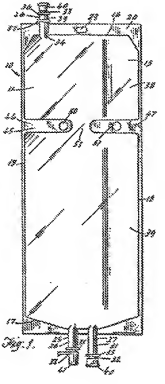
(54) **Compartmented flexible solution container.**

(57) A compartmented and collapsible container for sterile components which has at least two separate compartments for different components, yet will permit the intermixing of the components upon the release of a clamping member engaging an intermediate passageway which interconnects the compartments. The compartmented container is specifically constructed for use with two solutions which are normally incompatible over an extended period of time when mixed. The container herein described permits the two incompatible solutions to be sterilized in a disposable, flexible container. At the time of usage, the two materials can be readily intermixed in the same container and administered therefrom, such as with the usual intravenous administation equipment. An important feature of the container is a clamp member which can seal the interconnecting passageway in the container in a unique manner as well as a container with apertures to accommodate the clamp both during its operative and inoperative modes.



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COMPARTMENTED FLEXIBLE SOLUTION CONTAINER

Background of the Invention

This invention relates to a flexible container for materials which are normally incompatible when stored over extended periods of time. More particularly, the invention relates to a compartmented container wherein two incompatible materials can be sterilized in the flexible container and can subsequently be readily intermixed and administered in a safe and convenient manner.

Compartmented containers to accommodate different types of materials are well known in the art. It is also well known to provide clamping devices for compartmented containers. For example, in U.S. Patent 3,985,135 a hemostat or other type of clamping device is utilized to provide clamping action to seal off a passage between two compartments in a blood bag reservoir. An enteral feeding container with apertures to accommodate a clamp to sequester a portion of the fluid contents of a container is marketed by Corpak Company of Wheeling, Illinois. In U.S. Patent 3,809,224 a slotted retention member in the form of a clamp is utilized to separate a container lengthwise into two separate portions. Clamping members are employed in U.S. Patent 3,257,072 at the ends of heat seals in a flexible container for blood storage to provide temporary blockage between several compartments. Clamping-type devices for use in separating portions of containers which are temporarily folded are likewise disclosed in U.S. Patents 2,663,298; 2,756,874; 3,077,262; 3,082,867; 3,462,070; 3,639,952; 3,741,381; 4,023,675 and 4,282,863.

In the field of intravenous therapy, such as nutritionals, it is common practice to combine at least two aqueous based solutions such as dextrose and amino acids, and deliver them to the patient in one common infusion. Due to chemical reactivity in the autoclave

sterilization process or to degradation of the components over extended durations of time when mixed together, it has been necessary for the manufacturer to package the components separately. Historically, combination of the components occurs near time of use at a central hospital pharmacy. This can be a potentially hazardous procedure based on the technique used if the components of the container are exposed even briefly to the outside atmosphere. The procedure of combining the components at the hospital pharmacy requires special facilities, highly trained and conscientious personnel, valuable time, and hence an added burden of cost to the hospital especially in the situation where the hospital procures at least one of the components in bulk form and batch processes a multiple number of containers at once.

The prior art does not provide a mixing type multi-compartment container for intravenous solution which can be readily sterilized yet activated in a desired manner. This is due to the fact that there are inherent deficiencies in the prior art containers that either prevent them from being produced economically, fail to consistently function as desired or neglect to meet all end-user requirements.

It is an advantage of the present invention to provide a package or container separated into two compartments containing two components that would be intermixed at the time of use by means of opening a clamp member to allow the separated components to completely intermix with each other. Other advantages are a flexible intravenous solution container containing parenteral intravenous products to be intermixed and subsequently administered; a multi-compartment container wherein by means of opening a passageway between two compartments the contents of the two compartments can be intermixed in a controlled manner; a multi-compartment

container that is simple in design and able to be mass produced using existing technology, commonly used fabrication equipment and applicable to a wide range of materials; a container which provides a method of intermixing at least two I.V. solutions, so that when they are combined, maintenance of sterility is assured; and a method of combining two separated components for an admixture solution that is not time consuming, does not require special facilities, or highly trained personnel to activate.

Summary of the Invention

The foregoing advantages are accomplished and the shortcomings of the prior art are overcome by the compartmented flexible container of this invention for at least two different fluids wherein the fluids can be intermixed inside the container through the release of a clamping member opening a passageway between the compartments in the container. Two spaced-apart opposing walls formed from a plastic resinous material provide a body section with an intermediate section constructed with respect to the body member and the opposing walls to separate the inside of the body member into two separate compartments as well as to define a passageway between the compartments. A clamp member including a clamping portion has at least an arm portion with the arm portion adapted to be positioned over the walls defining the passageway to temporarily seal the contents of the compartments from each other. At least two apertures are spaced from the passageway with the apertures constructed and arranged to accept portions of the clamping member therethrough. When it is desired to intermix the contents of the container in the two separated compartments all that is required is to release the clamping portion of the clamp member from

the walls defining the passageway whereby the contents of the compartments will flow through the passageway and be intermixed.

In a preferred manner, the clamping member is defined by two opposing arm portions joined by a hinging portion and frictional engaging but release portions located opposite the hinging portion. Also preferably, the intermediate section is formed from seals having an aperture in each seal with one of the apertures adapted to receive the hinging portion of the clamp and the other frictional engaging portion. Also in the preferred manner, the container body member is fabricated from two separate sheets of thermoplastic material. The apertures are spaced in opposing directions from the passageway and in the intermediate seal portion.

In one embodiment of the invention the intermediate passageway is positioned adjacent the periphery of the container body member and in another it is centrally positioned.

Brief Description of the Drawings

A better understanding of the compartmented flexible container of this invention will be had by reference to the following description taken together with accompanying drawings, wherein:

FIGURE 1 is a view in side elevation showing the container of this invention prior to its being filled and without the intermediate clamping member.

FIGURE 2 is a view similar to FIGURE 1 except showing fluid materials in the two separated compartments of the container and with the intermediate clamping member secured thereto.

FIGURE 3 is a view in side elevation of the container shown in FIGURE 2.

FIGURE 4 is a top perspective view of one of the clamp members operable with the solution containers of this invention.

FIGURE 5 is a view in horizontal section taken along line 5-5 of FIGURE 2.

FIGURE 6 is a view in side elevation of another embodiment of the container of this invention.

FIGURE 7 is a view similar to FIGURE 6 showing still a further embodiment of the container of this invention.

FIGURE 8 is a view in horizontal section taken along line 8-8 of FIGURE 7.

FIGURE 9 is a top plan view of another clamp member operable with the containers of this invention.

FIGURE 10 is a partial view of the container illustrated in FIGURE 6 showing the compartment partially filled with different solutions.

Description of the Embodiments

Referring to FIGURE 1 of the drawing, the flexible compartmented container generally 10 includes a tubular body section 11 having a front wall 15 which at one end terminates in an end wall 17 and another end wall 16 at the opposing end. Extending from end wall 16 is hanger section 20 having an aperture 23 for engagement with the usual supporting hook (not shown). Extending through opposing end walls 16 and 17 are tubular ports 25, 26 and 27. Tubular port 26 includes an outer tubular member 34 with flange 37 and an outer portion 29 for receiving inner tubular member 33 with flange 36. Reseal cap 40 is placed over the end of tubular member 33. Extending through end wall 17 are ports 25 and 27 which also include outer tubular members

28 and 31 to which are secured inner tubular members 32 with flanges 35 therebetween. A protective cap 41 closes port 25 while a reseal cap 40 is placed on port 27. It will be noted that container 10 includes an intermediate section 45 formed by opposing seal portions 46 and 47 having apertures 50 and 51 therein. As indicated in FIGURE 1, front wall 15 and back wall 21 are left unsealed in the central area designated by the numeral 53 so as to provide a passageway between upper compartment 38 and lower compartment 39.

As shown in FIGURES 4 and 5 a clamp member 60 is described for use in closing passageway 53 by compressing opposing front 15 and back wall 21 together. This is effected when portions of the clamp 60 are fitted through apertures 50 and 51 which is best seen in FIGURE 5. Clamp 60 includes arm portions 61 and 62 with a hinge portion 63 between the leg portions and another hinged portion 64 attaching latch head 66. Flange 69 extends from an arm portion 62 as does an undercut 68 to provide engagement of undercut 65 and flange 67 of latch head 66. Two optional opposing pads 70 and 71 are positioned on arm portions 61 and 62. Guide surfaces 72 and 73 afford proper alignment for latch head 66 and flange 69. As indicated in FIGURES 2 and 3, a solution 80 such as an amino acid is placed in compartment 38 and a different solution such as dextrose is placed in compartment 39. They will be sealed from intermixing with each other by means of clamp 60 engaging unsealed walls 15 and 21 in the passageway area 53.

FIGURES 6 and 7 illustrate other embodiments of the invention which are referred generally by reference numerals 110 and 210. The same or similar parts are indicated by similar numbers except that they are in the "100" or "200" series. Only the different components or

features are discussed as the common elements and features will be obvious. Concerning container 110, it differs from container 10 in that the intermediate section 145 with the opposing and spaced apart sealed portions 146 and 147 does not include apertures or holes such as indicated at 50 and 51 for container 10. Instead, slits 142 and 143 are provided in sealed portions 146 and 147 with passageway 153 therebetween. Another distinction is in sealed portions 145 and 147 having curved wall sections such as indicated at 112 and 113. This will aid in directing the flow of the contents of compartment 138 in the direction of passageway 153. As indicated in conjunction with FIGURE 10, passageway 153 will be closed by means of clamp 160 portions of which will be inserted through slits 142 and 143. Clamp 160 will be closed when end portion 169 is engaged by flange 167 and undercut 165 so that pads 170 and 171 will press together the container front and back walls in the same manner as described in conjunction with container 10.

Concerning FIGURES 7 and 8, it will be seen that the major difference between containers 210, 10 or 110 is in the design of the intermediate section 245. In this instance, apertures 250 and 251 are employed similar to container 10 but sealed portion 246 is different in that it is in the form of an elongated projection with a slanted wall 214 extending over more than one-half the width of the container so as to result in passageway 253 being offset from the center in conjunction with opposing sealed portion 247. As is true of the previous embodiments, apertures 250 and 251 are spaced an appropriate distance apart to accommodate the clamp member 260 so that flange 267 will be accommodated through aperture 250 and hinge portion 263 will be accommodated through aperture 251. In this

position, flange 267 will be accommodated in undercut 268 with arm portions 261 and 262 pressing front and back walls 215 and 221 together so as to close passageway 253.

Fabrication

Containers 10, 110 and 210 will be fabricated in a similar manner from two sheets of thermoplastic material such as polyester. The opposing sheets will be sealed by opposing dies to provide sealed side walls 18 and 19 as well as end walls 16 and 17. During the sealing operation, appropriate cutting dies will also provide apertures such as 50 and 51 or slits 142 and 143. At the same time, sealing dies will form the sealed portions such as 46 and 47. Port sealing dies will secure the inner tubular members 28, 31 and 34 of ports 25, 27 and 26. The usual bag trimmers will be employed to sever the formed containers from the sealed sheet material.

Operation

The filling and using of the compartmented containers 10, 110 and 210 are substantially the same. Accordingly, only compartmented container 10 will be described and those particular features of containers 110 and 210 where they are different. Clamp 60 will be placed in intermediate section 45 by inserting arm portion 62 through either aperture 50 or 51 and then aligning latch head 66 and undercut 68 on opposing sides of the other aperture. Flange 69 will be engaged by latch head 66 as to assume a clamping action as seen in FIGURE 5. This will then press front wall 15 against back wall 21 to close off passageway 53. Compartments 38 and 39 can be filled to the desired degree with a suitable I.V. fluid material which can be placed therein

through the outer tubular members 34, 28 and 31 of open ports such as 25, 26 or 27. After filling to the desired degree, inner tubular member 33 with cap 40 prepositioned thereon will be solvent bonded to outer tubular portion 29 and similarly inner tubular member 32 with caps 40 and 41 positioned thereon will be solvent bonded to outer tubular members 28 and 31. Subassembled ports will be placed in the ends of their respective tubular members.

In a preferred manner, dextrose solution can be placed in compartment 39 and nutritional materials such as amino acid in compartment 38. The partially filled container will then be provided with an overwrap to environmentally protect from any external foreign contaminants, moisture loss, gas permeation, etc. and sterilized such as by autoclave sterilization. Further, depending upon sterilization cycle of each material, if the cycles are different, one compartment can be filled and sterilized and then the other compartment filled and sterilized. The container of this invention readily lends itself to this procedure.

When it is desired to utilize the container 10 with solutions such as 80 and 81 in their respective compartments 38 and 39 all that is required is to place the container 10 in a horizontal position and the disengagement clamp 60 such as by unlatching latch head 66 from undercut 68. This will open passageway 53 and allow the contents of the solution to intermix with all of the solution material then being placed in compartment 39. In the instance where a fluid material such as a powdered antibiotic material were to be placed in compartment 38, reseal cap 40 and port 26 will afford insertion of a needle of a hypodermic syringe so as to inject sterile water or other diluent into compartment 38 whereupon subsequent mixing such as by shaking the

container will afford thorough intermixing. Of course, in this instance the clamp 60 will be in the closed position and subsequently opened as previously described to allow the antibiotic solution to then mix with the contents of compartment 39. After thorough intermixing, the container can be supported from the usual hook such as by placing through aperture 23 and the protective cap then removed for administration port 25. The usual administration pin of an I.V. set will then be applied to port 25 and the mixed materials administered in the usual manner.

The use of containers 110 and 210 will be substantially the same as described for container 10 including the fabrication. The major difference is in the manner in which the contents of the upper compartments 138 or 238 are directed through passageways 153 or 253. The purpose of curved walls 112 and 113 are intended to ensure complete drainage into bottom chamber, as is true of slanted wall 214. The offset opening 253 allows easier access and manipulation of clamp, both in assembly and removal.

The preferred plastic resin for plastic sheet material forming the various compartmented containers 10, 110 and 210 is polyester. Other thermoplastic resinous materials such as polyolefins can be employed depending upon types of materials to be placed in the containers and the sterilization thereof. The preferred resinous plastic for forming the various tubular ports such as 25, 26 and 27 is polyvinyl chloride. However, other plastic tubing could be utilized depending upon sealing requirements and compatibility with the sheet plastic forming the various body sections of the containers. It will be noted in conjunction with clamps 60, 160 or 260, that pads such as 70 and 71 in clamp 60 and pads 170, 171 in clamp 160 are utilized. This can

be eliminated as can be seen in clamp 260 and still afford the requisite temporary sealing of passageway such as 253. While two ports such as 25 and 27 are indicated in communication with lower compartment 39 one single port with reseal capabilities could serve as additive and administration port or where an additive material is not desired to be placed in the compartment 39, a single administration port would be sufficient.

While the various containers have been described for use with an intravenous nutritional product, other applications for the container are numerous in the related medical field such as enteral feeding, continuous ambulatory peritonaal dialysis, chemotherapy, etc. Further, the compartmented container of this invention fulfills the need for a container in industries apart from the medical field such as food and beverage, cosmetics, adhesives, etc. While the containers of this invention have been described for use with a clamp and passageway to form a dual compartment container, it is obvious that several of the clamps and passageways could be provided in a container to form a multiplicity of compartments, the contents of which can be intermixed by opening the various clamp members in any preferred sequence.

It will thus be seen that through the present invention there is now provided a flexible container for any incompatible materials which is easily fabricated and readily utilized to mix the compartmented materials. The container with the clamp member can be activated with a minimum amount of effort yet provide a container system which will not be activated unintentionally. The container of this invention can be molded in various configurations to be adapted to numerous types of incompatible materials. The materials when placed in the various compartments of the container

are readily sterilized and will remain sterile after the desired intermixing. All of the foregoing is accomplished in the container which can be fabricated in the manner which does not result in substantial increased cost and accordingly, in a container system which is disposable.

The foregoing invention can now be practiced by those skilled in the art. Such skilled persons will know that the invention is not necessarily restricted to the particular embodiments presented herein. The scope of the invention is to be defined by the terms of the following claims as given meaning by the preceding description.

CLAIMS:

1. A compartmented flexible container for at least two different fluids wherein said fluids can be intermixed inside said container through the release of a clamping member engaging an intermediate passageway in said container comprising:

a body member defined by spaced apart opposing walls formed from a plastic resinous material;

an intermediate section constructed and arranged with respect to said body member and said opposing walls to separate the inside of said body member into two separate compartments as well as to define a passageway between said compartments;

a clamp member including a clamping portion defined by at least one arm portion, said arm portion adapted to be positioned over said walls defining said passageway to temporarily seal the contents of said compartments from each other; and

at least two apertures spaced from said passageway, said apertures constructed and arranged to accept portions of said clamping member therethrough;

whereby upon the release of the clamping portion of said clamp member from said walls defining said passageway, the contents of said compartments can flow through said passageway and be intermixed.

2. The compartmented flexible container as defined in Claim 1 wherein said intermediate section includes said apertures spaced in opposing directions from said passageway and said clamp is defined by opposing arm portions joined by a hinging portion and frictional engaging but releasable portions located opposite said hinging portion, with one of said apertures adapted to receive the hinging portion and the other said frictional engaging portions.

3. The compartmented flexible container as defined in Claim 1 wherein said container body member is fabricated from two separate sheets of thermoplastic material which are sealed at the periphery and said intermediate section is defined by two opposing sealed portions with said passageway positioned therebetween.

4. The compartmented flexible container as defined in Claim 1 wherein said apertures are positioned in said intermediate section and said clamp member is defined by two opposing arm portions joined by a hinging portion and frictional engaging but releasable portions opposite said hinging portion, and said apertures and said clamp member are constructed and arranged to receive portions of said clamp member therethrough and position said clamping portion over said passageway.

5. The compartmented flexible container as defined in Claim 1 wherein one of said apertures is positioned a greater distance from said passageway than the other.

6. The compartmented flexible container as defined in Claim 1 wherein said passageway is positioned adjacent the periphery of said container body member.

7. A compartmented flexible I.V. container for at least two different and incompatible I.V. fluids wherein said fluids can be intermixed inside said container through the release of a clamping member engaging an intermediate passageway in said container comprising:

a body member defined by spaced apart opposing walls formed from a plastic resinous material;

an intermediate section constructed and arranged with respect to said body member and said opposing walls to separate the inside of said body member into two separate compartments as well as to define a passageway between said compartments; and

a clamp member including a clamping portion defined by at least one arm portion, said arm portion adapted to be positioned over said walls defining said passageway to temporarily seal the contents of said compartments from each other; and

at least two apertures spaced from said passageway, said apertures constructed and arranged to accept portions of said clamping member therethrough;

an I.V. fluid material in one of said compartments;

a different and incompatible I.V. fluid material in the other of said compartments;

whereby upon the release of the clamping portion of said clamp member from said walls defining said passageway, the I.V. fluid materials will flow together and can flow through said passageway and be intermixed.

8. The compartmented flexible container as defined in Claim 7 wherein said container body section is fabricated from two separate sheets of thermoplastic material which are sealed at the periphery and said intermediate section is defined by two opposing sealed portions with said passageway positioned therebetween.

9. The compartmented flexible container as defined in Claim 7 wherein said intermediate section includes said apertures spaced in opposing directions from said passageway and said clamp is defined by opposing arm portions joined by a hinging portion and frictional engaging but releasable portions located opposite said hinging portion, with one of said apertures adapted to receive the hinging portion and the other said frictional engaging portions.

10. The compartmented flexible container as defined in Claim 9 wherein said apertures are positioned in said intermediate section and said clamp member is defined by two opposing arm portions joined by a hinging portion and frictional engaging but releasable portions opposite said hinging portion, and said apertures and said clamp member are constructed and arranged to receive portions of said clamp member therethrough and position said clamping portion over said passageway.

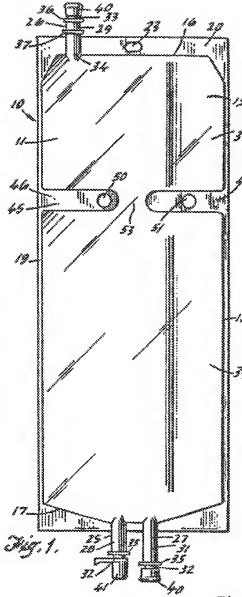

Fig. 1.

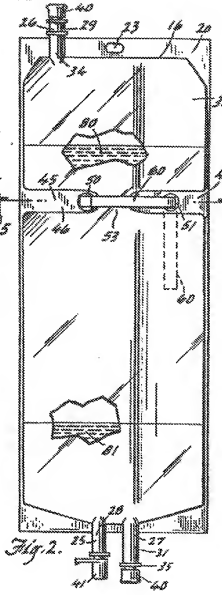

Fig. 2.

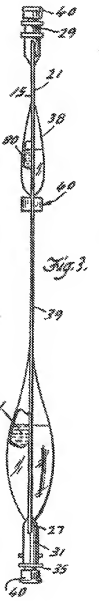

Fig. 3.

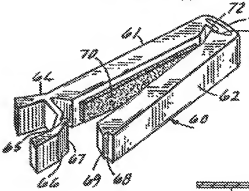

Fig. 4.

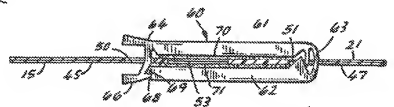

Fig. 5.

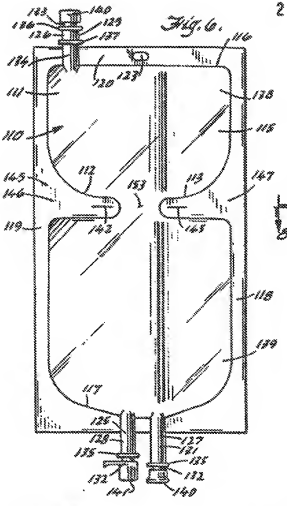

Fig. 6.

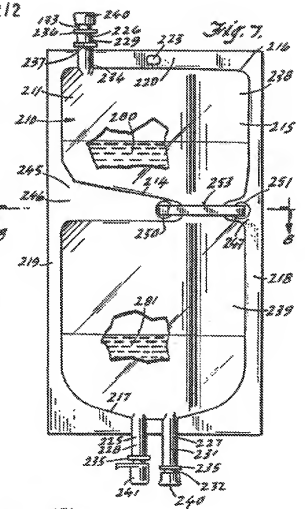

Fig. 7.

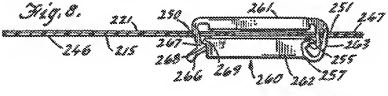

Fig. 8.

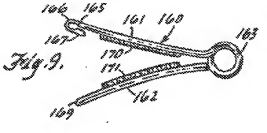

Fig. 9.

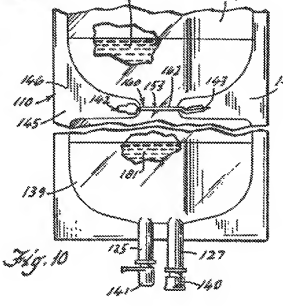

Fig. 10

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 132 632**
A3

(12) **EUROPEAN PATENT APPLICATION**

(21) Application number: 84107687.0

(22) Date of filing: 03.07.84

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(30) Priority: 21.07.83 US 515739

(43) Date of publication of application: 13.02.85
Bulletin 85/7

(84) Designated Contracting States: DE FR GB IT

(88) Date of deferred publication of search report: 29.05.85 Bulletin 85/22

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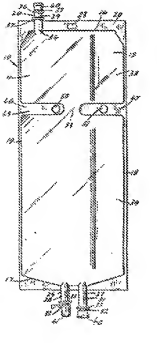

EP 0 132 632 A3

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European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 84 10 7687

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	GB-A-2 096 569 (ANATROS CORP.) * Figures 1, 2; claims 4, 6; column 2, lines 25-52 *	1,3,7,8	A 61 J 1/00 A 61 M 5/14
A	FR-A-1 035 491 (NICOLLE et al.) * Column 1; figures 1, 2; claims 1, 2, 5 *	1,7	
A	EP-A-0 067 794 (SOLCO BASEL AG.) * Figure 1; abstract; claims 1, 2 *	2,4,9,10	
A	DE-B-2 612 518 (BAXTER TRAVENOL LABORATORIES INC.) * Claim 1; figure 1; column 5, line 16 - column 6, line 3 *	1,6	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 J 1/00
A 61 M 5/14

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	23-01-1985	BARNY DE ROMANET P.M

CATEGORY OF CITED DOCUMENTS

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P : intermediate document

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